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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,904	09/18/2001	Jie Zhang	8747.82	8603
20551 7590 05/07/2007 THORPE NORTH & WESTERN, LLP. 8180 SOUTH 700 EAST, SUITE 200 SANDY, UT 84070			EXAMINER GEORGE, KONATA M	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 05/07/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 09/954,904	Applicant(s) ZHANG ET AL.	
	Examiner Konata M. George	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 08 June 2006.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-6, 11-14, 17 and 19-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 11-14, 17, 19, 22, 23 and 27-32 is/are rejected.

7) ☒ Claim(s) 2-6, 20, 21 and 24-26 is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 18 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/27/06</u> .	6) <input type="checkbox"/> Other: _____

U.S. Patent and Trademark Office
PTOL-326 (Rev. 08-06)

Office Action Summary

Part of Paper No./Mail Date 20070218

DETAILED ACTION

Claims 1-6, 11-14, 17 and 19-32 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on October 27, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Action Summary

2. The rejection of claims 1-6, 11, 12, 20-26 and 28-32 under 35 U.S.C. 102(b) as being anticipated by Zhang et al. and the rejection of claims 14, 19 and 27 under 35 U.S.C. 103(a) over Zhang et al. is hereby withdrawn with respect to applicant arguments.
3. The rejection of claims 1, 11-14, 17, 19, 22, 23 and 27-32 under 35 U.S.C. 103(a) over Hillman et al. in view of Bettinger is being maintained for the reasons stated in the previous office action.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. Claims 1, 11-14, 17, 19, 22, 23 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al. (US 5,383,848) in view of Bettinger (US 5,427,585).

Hillman et al. discloses using a heat pack in combination with a transdermal device to promote permeation of a drug (column 25, lines 41-67). Column 9, lines 11-29 teach that analgesics can be used in the invention. The prior art does not teach a temperature modification apparatus or the claimed temperature.

Bettinger discloses heating the skin with an electrode and resistor (col. 3, lines 8-14). It is also taught that it is known in the art to apply moist heat in order to increase blood flow (col. 3, lines 15-21).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combine teachings of Bettinger that heating the skin with an electrode and resistor increases blood flow with the heated drug pack of Hillman et al. One of ordinary skill would have realized that by heating the skin to increase blood flow and administering an analgesic through the skin via heat would help facilitate the delivery of the drug. With respect to the claimed temperature ranges, absent a clear showing of criticality, the determination of particular temperature ranges is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of the claimed composition.

Response to Arguments

5. Applicant's arguments filed June 8, 2006 have been fully considered but they are not persuasive.

Applicants argue that Hillman et al. fails to teach the use of a dermal drug delivery system as claimed in the instant invention. Applicant in the claims have not described what the dermal drug delivery system is, therefore, any composition containing a drug and is applied to the dermis can be construed as a dermal drug delivery system. Hillman et al. in column 25, lines 41-67 teach a vasodilator gel being applied to the skin, by the aid of a heat pack. It is taught by Hillman that a hot pack was applied to the skin prior to drug delivery. This limitation falls within the scope of the temperature modification apparatus being a separate device from the dermal drug delivery. Applicants argue that Bettinger uses electricity to deliver the drug to the skin. While this is true, the skin is heated prior to the delivery of the drug. The claims as written do not exclude the use of electricity from heating the skin prior to delivery of the drug. It is also argued that Bettinger does not teach a dermal drug delivery system as claimed in the instant invention. Applicant in the claims have not described what the dermal drug delivery system is, therefore, any composition containing a drug and is applied to the dermis can be construed as a dermal drug delivery system. It is argued that neither Hillman et al. nor Bettinger teach the requirement that the heat be applied at a predetermined temperature for a predetermined period of time. It is argued that the use of heat with transdermal administration is potentially dangerous and if left uncontrolled could cause serious consequences, including overdoses or death. While

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this is true, it is the position of the examiner that one of ordinary skill in the art of administering drugs transdermally would have the knowledge to formulate and deliver topically a composition that is safe and non lethal.

Allowable Subject Matter

6. Claims 2-6, 20, 21 and 24-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach the temperature modification device as claimed in claim 2.

Conclusion

7. Claims 1, 11-14, 17, 19, 22, 23 and 27-32 remain rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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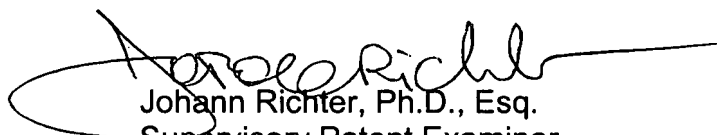
Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George
Patent Examiner
Technology Center 1600


Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600